IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327

ETHICON WAVE 6 CASES LISTED IN EXHIBIT A	JUDGE GOODWIN

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF JOHN R. WAGNER, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon") submit this response in opposition to Plaintiffs' motion to exclude general opinions of John R. Wagner, M.D. (Doc. 4876).

INTRODUCTION

Dr. Wagner has practiced urogynecology for approximately 30 years. Ex. A hereto, Curriculum Vitae at 1. In addition to being double board certified in Female Pelvic Medicine and Reconstructive Surgery and Obstetrics and Gynecology, he is certified by the American Association of Gynecologic Laparascopy and is an accredited member of the American Institute of Minimally Invasive Surgery. *Id.* A former Chief Resident, Dr. Wagner is a Fellow of the American College of Obstetrics and Gynecology. *Id.* A former preceptor for TVT courses, for several years he has taught pelvic surgery to residents in New York and has served as a Clinical Associate Professor for the Hofstra University School of Medicine. *Id.* at 2-4; Ex. B to Pl's motion, TVT Report at 1-3. Dr. Wagner has published several articles in peer-reviewed publications, and he has been asked to lecture about urogynecology topics throughout the country on many occasions. Ex. A hereto, CV at 2.

Dr. Wagner has performed numerous stress urinary incontinence ("SUI") surgeries throughout his career using a number of products and techniques, such as Kelly plications, Burch colposuspension, needle suspension procedures, autologous slings, and synthetic midurethral slings. Ex. B to Pl's motion, TVT Report at 1-2; Ex. C hereto, 3/13/17 Dep. 43:8-44:12. He has implanted more than 2,000 of Ethicon's devices for the surgical treatment of SUI, including approximately 600 to 800 TVT devices. *Id.* at 95:15-24, 120:11-23, 133:14-21; Ex. B to Pl's motion, TVT Report at 4, 36. He has also implanted approximately 800 to 1,000 Prolift +M devices, and he has explanted a number of pelvic mesh devices. *Id.;* Ex. F to Pl's motion, Prolift Report at 6.

In this wave of cases, Dr. Wagner has issued a general report related to Ethicon's TVT device and a general report related to Ethicon's Gynemesh PS, Prolift, and Prolift +M devices. Ex. B & F to Pl's motion. His opinions are based upon his education, medical training, clinical experience, extensive review of medical literature, position statements, guidelines, practice patterns, curricula, and various other materials. *Id.*; Ex. B hereto, Reliance Lists. In their motion, Plaintiffs have made vague challenges to certain aspects of Dr. Wagner's opinions. Dr. Wagner is well-qualified to offer the opinions set forth in his report, his opinions are supported by a reliable methodology, and Plaintiffs' challenges lack merit.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

I. The Court should allow Dr. Wagner to offer opinions about warnings.

In his reports, Dr. Wagner opines that Ethicon's instructions for use ("IFUs") adequately and accurately warned surgeons of risks, *taking into account risks that were commonly known*,

and therefore, were not required to be included in the IFUs. Ex. B to Pl's motion, TVT Report at 47-51; Ex. F to Pl's Motion, Prolift Report at 34-43. Dr. Wagner's opinions are consistent with the applicable legal standard, which imposes a duty to warn only of hidden medical risks not commonly known to pelvic floor surgeons. He is qualified to testify as to common knowledge among pelvic floor surgeons, whether or not certain medical risks exist, and the role that IFU package inserts play in the decision-making of a pelvic floor surgeon, all of which relate to this standard.

Dr. Wagner also explained that certain alleged risks, such as cytotoxicity and degradation, did not need to be included in the IFUs in order for the warnings to be complete because the medical literature and his experience has led him to conclude that those alleged risks do not cause any clinical consequences. Ex. B to Pl's motion, TVT Report at 49-50; Ex. F to Pl's Motion, Prolift Report at 42-43. He will also testify that IFUs are intended merely to "introduce somebody to a product" and that surgeons should rely on other sources, including medical literature, before implanting a pelvic mesh device. Ex. C hereto, 3/13/17 Dep. 89:4-21, 107:6-15, 109:1-8.

Dr. Wagner, who uses the IFUs to teach his residents, has based his warnings opinions on many sources, including his training and clinical experience, his extensive review of medical literature, his review of the FDA's "Blue Book Memo," his review of the IFUs, and his review of the TVT Surgeon's Resource Monograph. *Id.* at 87:1-5, 187:23-189:12; Ex. B to Pl's motion, TVT Report at 47-50; Ex. F to Pl's Motion, Prolift Report at 40-43. These are ample bases for his opinions on common knowledge, the existence of medical risks, and the role of the IFU in surgical practice, which justifies reliance on common knowledge.

Plaintiffs suggest that Dr. Wagner is not competent to testify about these issues because he does not have experience designing an IFU. Dr. Wagner has freely admitted that he is not a regulatory expert, and he will not opine on warnings from that perspective. Ex. D hereto, 9/25/17 Dep. 100:8-102:24. Dr. Wagner, however, will opine on the subjects identified above, which bear on an assessment of the IFU warnings from a clinical perspective, based on his knowledge of and clinical experience with these devices as well as his review of the literature. Plaintiffs do not challenge Dr. Wagner's clinical expertise or the sufficiency of his review of the literature.[1]

Consistent with the Court's prior rulings, Dr. Wagner, as a urogynecologist, "may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.,* 2016 WL 4582231, at *3 (S.D.W. Va. Sept. 1, 2016). Indeed, Dr. Wagner's reports and deposition testimony detail his extensive experience with these devices, including particular risks and complications he has experienced and researched, and his reports explain his opinions in detail. *E.g.*, Ex. B & F to Pl's Motion, Expert Reports.

Plaintiffs argue that the Court should exclude Dr. Wagner's warning opinions about TVT, because he supposedly only reviewed the 2015 version of the TVT IFU. *See* Doc. 4879 at 5 (citing Ex. E thereto, 3/13/17 Dep. 196:12-17). The citation, however, simply does not support Plaintiffs' assertion, and regardless, Plaintiffs' challenge otherwise lacks merit. For instance, Plaintiffs do not show that this has any bearing on Dr. Wagner's overarching opinion that it was

[1] Dr. Wagner testified that he broadly considered all medical literature and did not rely on one article to the exclusion of others. Ex. C hereto, 3/13/17 Dep. 179:4-12. He also utilized the Oxford Pyramid of Evidence in assessing the weight to be accorded to evidence. Ex. B to Pl's motion, TVT Report at 14-15; Ex. F to Pl's motion, Prolift Report at 16-18.

not necessary for the IFUs to include risks that were commonly known. To the extent that Plaintiffs take issue with Dr. Wagner's warning opinions, they may pursue those issues on cross-examination.

Finally, Plaintiffs claim that Dr. Wagner is not competent to testify that risks that did not appear on the IFUs were already commonly known to clinicians. Dr. Wagner will opine that the complications that Plaintiffs' experts claim should have been in the IFUs: (a) are risks that pelvic surgeons commonly knew, and therefore, need not be warned about; (b) are not genuine complications; or (c) are not attributable to the device. *E.g.*, Ex. B to Pl's Motion, TVT Report at 47-51; Ex. F to Pl's Motion, Prolift Report at 40-43.[2]

Plaintiffs claim that Dr. Wagner's opinions about what risks were commonly known are unreliable, because he "has never done any kind of survey or used any kind of formal methodology to determine what physicians did or not did not know with regard to the pelvic mesh devices." Pl's Brief, Doc. 4879 at 6. But Plaintiffs do not cite to any authority that would require an expert to conduct any type of formal study to support an opinion such as this. Nor have Plaintiffs' experts conducted any kind of survey to support their opinions that certain risks were not commonly known.

[2] The law imposes no duty to warn sophisticated users of products with respect to risks that the sophisticated users already know or should know. *See, e.g.*, Restatement (Third) of Torts: Product Liability § 2 cmt. j (1998); Restatement (Second) of the Law of Torts § 402A cmt. j; American Law of Product Liability 3d § 32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990). In fact, 21 CFR § 801.109(c) states there is no duty to warn if "the article is a device for which the hazards, warnings and other information are commonly known to practitioners licensed by law to use the device." This is an objective test not dependent on the knowledge of the individual surgeon, and Dr. Wagner is certainly competent to share his opinions about what risks should be obvious to surgeons who use the devices and how a clinician skilled in the art of pelvic floor surgery would construe the IFUs. Indeed, Ethicon writes its IFUs for pelvic floor surgeons like Dr. Wagner. Under the learned intermediary doctrine, such surgeons are the ones who must be adequately warned.

When questioned about this during his deposition, Dr. Wagner revealed the silly nature of Plaintiffs' proposition:

> Q. Have you done any kind of study or analysis to determine what percentage of pelvic floor surgeons did in fact know of all these risks between 2005 and 2012?
>
> A. That's a funny question because it's an inherent part of the training. I mean, if you look at the surgical training that we receive as residents and then as fellows, people that do this type of surgery, this is part of the training. It's in the textbooks. It's in, you know, Te Linde's operative Gynecology. The complication rates, wound healing, these are all subjects that are part of normal surgical training. It's in Danforth's books on operative gynecology. So it's part of our board questions. It's part of our -- it's part of what we're tested on. So, to have a study on something that's supposed to be inherent to what you know, so you're asking sort of the question -- is the question is there post-marketing surveillance on whether the pelvic reconstructive surgeons have learned what they're supposed to have learned? Is that what the question is, in a way?
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> Q. Well, my question is have you ever done any kind of study or analysis to determine what percentage of pelvic floor surgeons did in fact know of all these risks in, say, 2012?
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> A. Again, that's such a funny question. No, I've never done a study that looks at whether the pelvic floor surgeons learned what they were supposed to learn about pelvic floor surgery. It just doesn't make sense to me, that question.
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> Q. So, when you say that they are widely known by surgeons, is it your opinion that 100 percent of pelvic floor surgeons know of all these risks, or not?
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> MS. KABBASH: Objection.
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> A. I would like to think that my field is perfect, but I'm sure it's like every other field. There's probably not competent people in my field, just like there's not competent lawyers and not competent firemen and not competent cops. But what you're asking is part of our inherent training, and so if I -- if I could assert the word "competent" and "well-trained," then yes, the answer would be 100 percent.
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> Q. So, it's your opinion that if a physician in a particular case testified that he didn't know of one or more of these risks when he implanted the Prolift that that physician wasn't competent?
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> MS. KABBASH: Objection.
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> A. I'm not sure what risk you're referring to because our initial discussion was talking about general risks of vaginal surgery. So if we're –

> Q. I'm referring to any of the risks that you have listed in paragraph 1 of page 34 of your report.
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> A. Yes, I think that a pelvic surgeon who does pelvic reconstructive surgery realizes that that list of things that I laid out there are potential complications of pelvic repair surgery with or without using mesh. And I would be surprised, and maybe I'm thinking too highly of my own field, that if a board certified urogynecologist in pelvic reconstructive surgery didn't know those things, I would certainly be disappointed.
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> * * *
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> A. Well, I don't know of a post-marketing surveillance study of doctors. By post-marketing, I mean like I'm saying it almost in jest because it would be post-marketing of their medical training. I just -- I don't know of – I don't know of any study, and I certainly did not conduct a study to look at my colleagues to see whether they understood the basics of vaginal surgery. I just --it's a funny question, is my best answer.

Ex. D hereto, 9/25/17 Dep. 83:8-89:19

Dr. Wagner further explained that his opinions were based "on any analysis of the published medical literature to assess what risks were reported on and available in the publicly available medical literature," as well as what is in textbooks and included as part of surgical training. *Id.* at 127:3-129:5.

Dr. Wagner's opinions are reliably based on his clinical experience as well as his thorough critique of scientific literature. *See, e.g., id.*; *see also Huskey*, 29 F. Supp. 3d at 734-35 (allowing Dr. Johnson to testify about evidence of absence because his opinions were also based on medical literature); *Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *12 (S.D. W.Va. Apr. 28, 2015). If Plaintiffs intend to argue at trial that Ethicon's IFUs failed to disclose certain risks, then it is only fair that Ethicon be allowed to defend itself by demonstrating that those risks were obvious to the users of the product (pelvic surgeons and urologists), and therefore, did not need to be included in the IFUs in accordance with the aforementioned law.

II. The Court should allow Dr. Wagner to provide certain design and scientific property opinions.

Despite Dr. Wagner's qualifications as a urogynecologist, Plaintiffs argue that he is not competent to provide opinions about the "design and the material properties of Ethicon's TVT device." Doc. 4879, p. 7. The only opinions that Plaintiffs claim to fall within this category are opinions about "degradation, weight, porosity, and cut (laser or mechanical)." *Id.* at 9. Plaintiffs' argument is vague and generic. For instance, in support of their argument that he "arbitrarily offers opinions regarding the design and the material properties of Ethicon's TVT device," Plaintiffs cite Dr. Wagner's entire report. *Id.* at 7 & n. 7. The Court should deny Plaintiffs' motion for lack of specificity and otherwise determine that Dr. Wagner is competent to render opinions that may touch upon design and material properties.

A. "Design" Opinions

Dr. Wagner does not purport to be an expert on the design process. As noted by Dr. Wagner, he is a design expert only from a clinical perspective based on his clinical experience and review of the literature. *See* Ex. C hereto, 3/13/17 Dep. 148:16-150:4, 187:15-22. In rejecting a similar challenge to one of Ethicon's other urogynecologist experts, Dr. Michael Woods, the Court noted that Plaintiffs' motion is "plagued with confusion about what constitutes a design opinion," and found that "Dr. Woods has not expressed any opinions about the process of designing a product." *In re: Ethicon*, 2016 WL 4582231, at *3. As with that case, the Court should deny Plaintiffs' challenge as "moot." *Id.*

To extent that Plaintiffs have appropriately challenged Dr. Wagner's ability to opine that the PROLENE mesh in TVT is of the appropriate weight and porosity, Plaintiffs' challenge lacks

merit. *See* Ex. B to Pl's motion, TVT Report at 34-35, 45-46. Dr. Wagner appropriately bases his opinion on his clinical experience and review of the medical literature. *Id.*

Plaintiffs fault Dr. Wagner for "applying no objective, measurable standard to arrive at his conclusion that a mesh is lightweight." Doc. 4879, p. 9. But the term "lightweight" is not a scientific term and whether something is considered "light" or "heavy" does not lend itself to an objective scientific formula, but instead, is inherently comparative by nature. In any event, Dr. Wagner's opinion that the mesh in Ethicon's devices at issue is "light" is consistent with the medical literature that he has reviewed. *See* Ex. D hereto, 9/25/17 Dep. 121:5-122:7 (citing Ex. E hereto, Jones, K. *Tensile Properties of Commonly Used Prolapse Meshes*. Int Urogynecol J 2009; 20: 847-853.

Further, Dr. Wagner is well-qualified to explain that the Okulu study cited by Plaintiffs' experts "provides no credible basis to conclude that [alternative] materials would be safer than the Prolene mesh in TVT." Ex. B to Pl's motion, TVT Report at 46. If Plaintiffs' expert clinicians are allowed to reference this study, fairness dictates that Dr. Wagner be allowed to explain to the jury that this study is inapposite.

Dr. Wagner is also well qualified to testify that there is no increased risk of safety issues based on the manner by which the mesh is cut (whether by laser or machine). Dr. Wagner bases his opinions on his personal clinical experiences, as well as his review of the medical literature. *Id.* at 45-46; Ex. C hereto, 3/13/17 Dep. 131:20-133:13, 163:4-167:23. As noted by Dr. Wagner, "I have searched for literature that comparatively studies tapes with mechanical cut vs. laser cut mesh and have found none, much less one that concludes that a particular method of cutting has a bearing on the safety of the device." Ex. B to Pl's motion, TVT Report at 46.

B. "Properties" Opinions

Plaintiffs also vaguely argue that, because he is not a pathologist or a biomedical engineer, Dr. Wagner is not competent to testify about degradation and other unspecified issues touching upon mesh properties. The Court has consistently found similar challenges to be "without merit" and noted that the Defendants' urogynecologist experts' "extensive clinical and research experience qualifies [them] to opine on mesh's reaction to and effect on the human body, and relatedly, the safety and efficacy of mesh products." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 45493666, at *3 (S.D.W. Va. Aug. 25, 2016); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4556807, at *4 (S.D.W. Va. Aug. 31, 2016).

Dr. Wagner's opinions about degradation are summarized on pages 33-38 of his TVT report. Ex. B to Pl's motion. His opinions are not at the molecular level and the equivalent of the opinions of a biomedical engineer or polymer chemist, but instead, focused on clinical aspects of alleged degradation. *See Wilkerson v. Boston Scientific Corp.*, 2015 WL 2087048, at *20 (S.D. W. Va. May 5, 2015) ("That he has no experience in polymer science is irrelevant because Dr. Porter is not offering opinions about 'what's happening at the molecular level'"). According to Dr. Wagner: "I've watched how [the PROLENE mesh in TVT has] performed not only in my patients, but also how it's performed through the vast years of medical literature and studies have been done on it." Ex. C hereto, 3/13/17 Dep. 184:23-185:14. He states, for instance, that, based on his extensive clinical experience, "I have never seen any evidence of degradation of polypropylene mesh." Ex. B to Pl's motion, TVT Report at 36. His review of the medical literature has bolstered his conclusion that mesh does not degrade and that, even if it did, it does not do so "in any way that manifests clinically for patients." *Id.* at 35.

In these MDLs, the Court has allowed urologists and gynecologists with similar qualifications as Dr. Wagner to testify about degradation and other issues touching upon properties. For instance, in *Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, at *45 (S.D. W. Va. Apr. 28, 2016), the plaintiff argued that Dr. Michael Douso, a urogynecologist, was not qualified to testify about the physical properties of mesh and to offer opinions about degradation and similar topics because he was not a biomaterials or polymer science expert. In rejecting this challenge, the Court stated as follows:

> As to qualification, Dr. Douso is a practicing urogynecologist, and he is board-certified in obstetrics and gynecology. He has extensive experience with BSC's produces for treating SUI and POP, including use of the Prefyx and Uphold mesh sling devices. Dr. Douso has had extensive experience teaching minimally invasive surgical techniques and procedures to physicians across the United States, including implantation of the defendant's polypropylene mesh devices. Simply because Dr. Douso is not an engineer, chemist, or biomechanical expert does not render him unqualified to testify that he has not experienced mesh degradation, contraction, or a foreign body response in his practice. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc.*, 878 F.2d at 799. I **FIND** that Dr. Douso's extensive experience qualified him to testify that he has not experienced certain alleged physical properties in the defendant's Uphold and Prefyx devices.
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> * * *
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> The literature on which Dr. Douso relies includes multiple studies regarding polypropylene mesh devices and on the body's post-operative reaction to the mesh.
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> The court has permitted physicians in related cases to offer similar opinions based on their clinical experience and review of the scientific literature. *See Tyree*, 54 F. Supp. 3d at 585 (finding an expert's "clinical experience and review of the scientific literature are sufficiently reliable bases in forming this particular opinion"). Accordingly, I **FIND** that Dr. Douso's extensive clinical experience

> and literature review provide a sufficient reliable basis for his opinions. The plaintiff's motion on this point is **DENIED**.

2016 WL 1718836, at *46 (other citations omitted); *see also id.* at *5 (finding that urologist Niall Galloway's "clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage and contraction"); *id.* at *33 (allowing testimony of defense expert Patrick Culligan, M.D.); *Huskey*, 29 F. Supp. 3d at 706-07, 735 (rejecting similar challenges to plaintiff expert Bruce Rosenzweig, M.D., and defense expert urogynecologist Harry Johnson, M.D.); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 550, 585 (S.D.W. Va. 2014) (rejecting similar challenge of plaintiff expert Donald Ostergard, M.D. and defense expert Lonny Green, M.D.); *Jones v. Bard, Inc.*, No. 2:11–cv–00114, [Doc. 391], pp. 6–9.

Under Plaintiffs' own theory, if Dr. Wagner is not competent to testify about these particular issues touching upon design and mesh properties, then none of Plaintiffs' clinician experts in these cases are competent to opine on these issues.

III. The Court should allow Dr. Wagner to testify about the safety of Prolift.[3]

Although Plaintiffs do not challenge Dr. Wagner's competence to testify about the safety of TVT, they challenge his competence to testify about the safety of Prolift. According to Plaintiffs, "Dr. Wagner's use of mesh products, and his qualification as a gynecologist and pelvic floor surgeon do not, by themselves, uniquely qualify him to opine regarding the safety and efficacy of a medical device—any more than a licensed driver is qualified to opine about the safety of a vehicle based on how it feels when he drives it." Doc. 4879, p. 9. If the Court

[3] Although Dr. Wagner's pertinent report addresses Gynemesh PS, Prolift and Prolift +M, Plaintiffs' brief simply references the "Prolift product." Doc 4879, p. 9. Therefore, in the interest or brevity, this section of Ethicon's brief only references the Prolift device, although Ethicon's arguments are equally applicable to the other two devices.

accepts Plaintiffs' argument, it should find that every single one of Plaintiffs' clinician experts in these cases is unqualified to critique the safety of Ethicon's medical devices.

As with many other urogynecologist experts in this case, Dr. Wagner's opinions are based on his extensive clinical experience, his training, and his comprehensive review of the medical literature. Plaintiffs, however, claim that "[a] review of the literature does not provide sufficient basis for Dr. Wagner to offer a reliable design opinion unless he can identify an appropriate standard that he applied." Doc. 4879, pp. 9-10. The only authority cited by Plaintiffs for this contention is *Winebarger v. Boston Scientific Corp.*, 2015 WL 1887222, at *14 (S.D.W. Va. Apr. 24, 2015). But in that case, the Court merely found that a urogynecologist, Dr. Bobby Shull, was not competent to testify about medical device structural designs because he had not reviewed "standard operating procedures for BSC's medical device development."

Here, Dr. Wagner is not seeking to discuss design protocols related to product development. Instead, he merely intends to testify that Prolift is safe and effective for the treatment of pelvic organ prolapse.

There simply is no basis for Plaintiffs to attack Dr. Wagner's opinions merely because he is unwilling to commit to a specific numerical baseline. Plaintiffs suggest that a product is inherently unsafe if it has a high complication rate. But, as Dr. Wagner explained, even a product with a 100% complication rate could be safe if the complications are minor. Ex. D, 9/25/17 Dep. 112:20-113:3. Suppose, for instance, that a particular vaccine is extremely effective at preventing polio and its only side effect is that it temporarily causes a minor sore throat for 100% of patients for approximately a day after administration. Under Plaintiffs' logic, that vaccine is unsafe and should not be marketed.

During his explanation, Dr. Wagner demonstrated the silly nature of Plaintiffs' proposition:

Q. How high would the complication rate need to be on the Prolift before you decide that its complication rate was unacceptable to you?

MS. KABBASH: Objection.

A. That's a almost -- there's no rate here. It's almost impossible to -- to put a number like that. This isn't a number -- this isn't a number thing.

I can tell you that the use of Gore-Tex for sacrocolpopexies was associated in the literature with higher rates of complications than other products, and we have good meta-analysis, good long-term data, high levels of the pyramid data showing complication rates associated with Prolift, and I'm happy with that complication profile, and I think for the appropriate selected patients, it's an excellent procedure, and it was an excellent procedure.

Q. So, what objective standard are you applying to determine that the Prolift is safe and effective while concluding that the Gore-Tex is not safe and effective?

MS. KABBASH: Objection.

A. The objective standard is – is the objective standards that form my medical opinions: my training, my surgical training, my surgical experience, my teaching, my review of the literature, my attendance at conference, my review of cases presented at conference. The body of medical literature that exists out there is my objective standard. And then as I said in my expert report, rating that body of literature based on quality of evidence is my objective standard.

Q. So, in terms of complication rate, you'd agree with me that there's no numerical number of complications that you can give me to where you'd feel that the Prolift device was not safe and effective, right?

MS. KABBASH: Objection.

A. I think that there are -- it's hard to separate the individual from the procedure. There were clinical situations where native tissue repairs are appropriate, where mesh repair is appropriate vaginally, where an abdominal mesh repair is appropriate, and I don't think we're trying to pound all patients through the same operation. If there's a surgeon doing only one operation, then I don't think they're serving their patients well.

You know, it's like -- and in terms of complication rates, you know, we give poisons to people who have cancer because -- because the complication rate of the cancer is much greater than the complication rate of the poison we're giving them. So it's always a measure of what you're treating them versus the complication rate. I wouldn't give somebody, you know, Cytoxan, which is a poison, even if it did treat pelvic prolapse because I have much lower risk -- lower risk treatments for that, but if they have breast cancer, yeah, I'm going to give them that otherwise the breast cancer's going to kill them.

So, we're always relating what we're treating people with to the underlying disease process and we're looking to benefit the patient overall.

Q. Well, here we're talking about pelvic organ prolapse and the Prolift.

A. Right.

Q. So, how high would the complication rate need to be for a device to treat pelvic organ prolapse before you'd say this isn't acceptable to me, it's not safe and effective?

MS. KABBASH: Objection; asked and answered.

A. I agree. I think I've answered it.

Q. So even if the complication rate were 100 percent, it could potentially be, the Prolift could potentially be safe and effective applying your standard?

MS. KABBASH: Objection.

A. Again, I think we're looking at the published literature, the rates of complications as we know it compared to other procedures, including non-treatment and analyzing the patient and her disease process in light of all of that and providing options.

Q. And there's no numerical standard that you can articulate as you sit here today to where you would determine the Prolift or a device like the Prolift to not be safe and effective?

A. I don't think of it as just a numerical standard like that.

MS. KABBASH: Objection.

A. It's way too broad. It's way too -- it's clinically useless because complications could be anything from, you know, the most minor thing to life-

> threatening. So you can't even put a number on it 'cause complications could be anything. It's just not a credible -- it's not a realistic way to look at this.

Id. at 108:6-113:3 (emphasis added).

Plaintiffs also ignore that none of their clinical experts has claimed that an objective numerical baseline exists.

Finally, Plaintiffs suggest that Dr. Wagner's opinions somehow are not reliable because he may not have closely reviewed every single work referenced on his reliance list. But Dr. Wagner's report cites numerous scientific articles that support his opinions. Ex. F to Pl's motion, Prolift Report at 16-28. Indeed, he has reviewed a "vast amount of literature" that support his opinions, as well as literature that does not support his opinions. Ex. D, 9/25/17 Dep. 14:2-17:16. In fact, he conducted a presentation on the Gynemesh PS mesh as part of an American College of Obstetricians and Gynecologists conference. *Id.* at 31:8-32:12.

That review of the literature, accompanied by Dr. Wagner's training and expertise, render him well qualified to testify about the safety of Prolift. Plaintiffs' challenge lacks merit.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that the Court deny Plaintiffs' motion to exclude Dr. Wagner's opinions.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this day, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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